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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,326	12/31/2003	Jeffrey O. Saunders	VPI/02-05 US	4684

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VERTEX PHARMACEUTICALS INC.  
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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT PAPER NUMBER

1624

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/750,326

Applicant(s)

SAUNDERS ET AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 5-5-06 (Election).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 10-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8-29-05</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's election without traverse of Group I (claims 1-7 and 9 (in part)) in the reply of 5-5-06 is acknowledged. Applicant has also elected compound 14 (specification page 44).

Claims 8 and 10-16 are withdrawn from consideration as being drawn to the non-elected subject matter.

Claims 1-7 and 9 are considered herein.

#### ***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-7 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 1 recites the phrase "optionally substituted" which renders the intended groups indefinite metes and bounds. In the absence of the specific moieties intended to effectuate modification by "substitution" or attachment to the chemical core claimed, the term "substituted" renders the claim in which it appears indefinite in all occurrences wherein applicant fails to articulate by chemical name, structural formula or sufficiently distinct functional language, the particular moieties applicant regards as those which will facilitate substitution, requisite to identifying the composition of matter claimed.

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b. In the definition of R<sup>8</sup>, the limitation of “amino protecting group” has indefinite metes and bounds because it is unclear what functional groups, rings or combination of both would constitute such an “amino protecting group”. It is also not clear if the scope of R<sup>8</sup> includes all the groups recited for R<sup>6</sup>.

c. Claims 2-7 and 9 are rejected as being dependent on claim 1 and carrying over the indefinite limitations.

d. Claim 7 recites the phrase “According to another preferred embodiment” which renders the claim indefinite because it is not clear if the limitation followed said phrase is part of the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by **Fujimori et. al.** (EP 456,835). Compound #91 reads on the claimed formula I with the following substituents:

A is an aryl group (i.e., benzo);

R<sub>a</sub> is –COOH;

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$R_1$  is hydrogen;  $n = 1$ ;

$R_2$  is an arylaliphatic wherein the aryl group is substituted (i.e., fluorobenzyl);

$R^3$  is chloro, and  $R^4$  is hydrogen.

Note, the proviso excludes the compound wherein  $R^3$  is hydrogen, and not chloro.

Also, compound #113 (page 21) and compound #161 (page 24) read on the claimed formula I with the following substituents:

A is an aryl group (i.e., benzo);

$R_a$  is  $-\text{COOH}$ ;

$R_1$  is hydrogen;  $n = 1$ ;

$R_2$  is an arylaliphatic wherein the aryl group is substituted;

$R^3$  and  $R^4$  – each is an alkoxy group (i.e., each is  $R^{11}$  which in turn is  $-(\text{CH}_2)_m\text{-Y}$ ;

wherein  $m = 0$ , and Y is  $\text{OR}^6$ ;

$R^6$  is an alkyl group);

Or  $R^3$  is  $R^{15}$  which is a heterocyclyl group, and  $R^4$  is hydrogen.

The disclosed compounds are used to inhibit platelet aggregation. Thus, the pharmaceutical composition in the instant claim 9 is also anticipated.

3. Claims 1-7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by **Malamas et. al.** (J. Med. Chem., 1991, Vol. 34, pp. 1492-1503 – cited on IDS). Compound #17 reads on the claimed formula I with the following substituents:

A is an aryl group (i.e., benzo);

$R_a$  is  $-\text{COOH}$ ;

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$R_1$  is hydrogen;  $n = 1$ ;

$R_2$  is an arylaliphatic wherein the aryl group is substituted (i.e., fluorobenzyl);

$R^3$  is bromo, and  $R^4$  is hydrogen.

Note, the proviso excludes the compound wherein  $R^3$  is hydrogen, and not bromo.

4. Claims 1-3 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by **Gordeev et. al.** (Tet. Let., Vol. 38, No. 10, pp. 1729-1732 – cited on IDS). Compound #8h reads on the claimed formula I with the following substituents:

A is an aryl group (i.e., benzo);

$R_a$  is  $-\text{COOH}$ ;

$R_1$  is arylaliphatic;  $n = 1$ ;

$R_2$  is an heterocyclaliphatic (i.e., (Morpholin-4-yl) $\text{CH}_2\text{CH}_2$ );

$R^3$  is chloro, and  $R^4$  is hydrogen.

Again, the proviso excludes the compound wherein  $R^3$  is hydrogen, and not chloro.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Fujimori et. al.** (EP'835).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Besides compounds #91, #113 and #161, Fujimori et. al. also disclose other species that read on various aspects of the invention including many substituents corresponding to the instant  $R^3$  and  $R^4$  as well as many group corresponding to the instant  $R_2$ . Furthermore, the reference's generic formula I on page 3 provides equivalency teaching for numerous substituents corresponding to  $R_2$ ,  $R^3$  and  $R^4$  – see the definitions of  $R^1$ - $R^3$  of the reference.

Thus, the skilled chemist would have been motivated to make other compounds of the claimed formula I because said compounds would have been expected to inhibit platelet aggregation as well.

Thus, at the time that the invention was made, it would have been obvious to make and use compounds of the claimed formula I in view of the teaching above.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (9:30-6:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



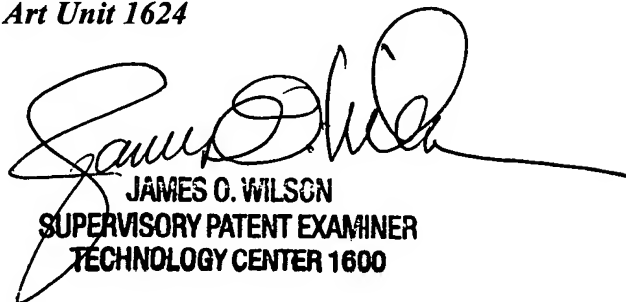
**Tamthom N. Truong**

**Examiner**

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\*\*\*

7-17-06



**JAMES O. WILSON**  
**SUPERVISORY PATENT EXAMINER**  
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